REMARKS/ARGUMENTS

Claim amendments

Claims 3-9 and 11-20 are under examination in the application, with Claims 1, 2 and 10 canceled.

Claims 3 and 5 are hereby amended. Claims 11, 14 and 15 are hereby canceled. New Claims 21 and 22 are added.

Claim 3 is amended to more particularly describe the invention as a test meal composition, and to provide that the sucrose behenate is 0.1% to 10% by weight of the total of dietary fat and sucrose polyester (support from Claim 11, now canceled).

Claim 5 is amended to provide that: the test meal comprises a predetermined amount of dietary fat and a predetermined amount of the marker (support from Claims 1 and 2 as originally filed); collecting a sample portion of fecal matter from the stool of the subject (support at paragraph [0030], last sentence, and paragraph [0038]); a step of analyzing for the amount of total fatty acid in the dietary fat and the amount of behenic acid in the sucrose behenate recovered in the fecal sample portion (support in paragraphs [0047] to [0049], which describe saponifying the fecal sample portion, and measuring the amount of fatty acids in the saponified fecal sample portion); and the step of calculating provide calculating the amount of dietary fat recovered from the test meal based on the measured amounts of total fatty acid and behenic acid.

New Claims 21 and 22 provide that the amount of collected fecal sample portion is from about 10 milligrams to about 2 grams, and from about 10 milligrams to about 20 milligrams, respectively (support in paragraph [0038]).

All amendments and new claims are fully supported by the disclosure of the specification as filed. Applicants respectfully request entry of the amendments.

Re-opening of Prosecution

The Action indicates that prosecution of the application has been re-opened to present new grounds of rejection. For clarification, every art-based rejection in the last office action has been withdrawn, and are presumed to have been overcome by argument or distinguished in the claims as amended.

Rejection of Claims under 35 USC 112, 2nd paragraph

Claims 3-4, 6 and 11-12 are rejected as indefinite, because the percentage of the marker is not specified, while the levels of dietary fat, protein and carbohydrates are specified.

Regarding test meal composition Claims 3-4 and 11-12, without acquiescing whatsoever to the merits of the rejection, Applicants have amended Claim 3 to include the feature of dependent Claim 11 (and have canceled Claim 11), wherein the weight percent of the dietary fat, sucrose polyester comprising sucrose behenate, protein and carbohydrate are each specified.

Regarding method Claim 6, Applicants traverse. Specifying in a dependent claim the specific levels of only the protein and carbohydrate in the provided test meal does not make the claim indefinite. The claims clearly set forth the metes and bounds of the patent protection desired and required of the claimed method. Clarification is requested.

Rejection of claims under 35 USC 103(a)

Claims 3 and 11 are rejected as obvious over Young (US 5,085,884).

Applicants traverse, notwithstanding the amendment to Claim 3.

Young teaches a fat composition consisting of ordinary digestible fat and a non-absorbable fat consisting of both a liquid (MP < 37°C) polyol polyester, and a solid polyol polyester (MP > 37°C). Contrary to the assertion made in the Action, Young only teaches that the fat compositions can include bulking agents such as partially or wholly non-digestible carbohydrates, gums, starches, etc., and dietary fibers. No levels are disclosed for such bulking agents.

Young further teaches that the fat composition can be used to make "potato chips and other low moisture foods" that contain the fat composition (see column 19, lines 22-24, emphasis added) and other nonfat ingredients (e.g., carbohydrates, protein, etc.). While the food compositions of Young may be low calorie and may "comprise" the fat composition, there is no express description or teaching in the Young patent of a predetermined amount of digestible fat in the food composition, or of a predetermined amount of non-digestible fat marker, as required by the Applicants' claims. Young teaches that the potato chips have the fat composition applied in a variety of ways, including immersing, dipping, soaking, spraying, blowing, pouring, etc, etc, and that the fat composition is typically absorbed into the interior of the food (see column 19,

lines 41-61), which a person of ordinary skill would recognize does not define a predetermined amount of each material in the alleged test food.

Young provides no express teaching or suggestion of providing a test meal that includes the claimed levels of proteins and carbohydrates of the claimed invention. The rejection states that "Young fails to teach of the same percentage amounts of the nondigestable marker, dietary fat, carbohydrate and protein as recited in the instant claims." In fact, Young makes no disclosure of the range of levels of sucrose polyester, dietary fat, carbohydrate and proteins" in a food, and only mentions the amount of moisture (column 19, lines 22-30). In terms of a disclosure of a food, Young teaches essentially a potato chip that includes the fat composition, and "other" low moisture foods, implying "other low moisture foods like potato chips" (emphasis added). The present invention described in Claim 3 requires predetermined amounts of the dietary fat and the sucrose polyester comprising sucrose behenate. The "predetermined amounts" of the dietary fat and sucrose polyester comprising sucrose behenate, are not recognized in the Young reference as result-effective variables, and therefore arriving at Applicants' claimed invention from the general disclosure in Young of fat compositions and low moisture foods containing fat compositions and other nonfat ingredients cannot be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)

In conclusion, a person of ordinary skill would not understand that Young describes or makes obvious a test meal composition that includes a predetermined amount of dietary fat, a predetermined amount of a sucrose polyester comprising sucrose behenate, along with protein and carbohydrates in the claimed ranges.

Claims 5-9 and 13-20 are rejected as obvious over a combination of Janghorbani (US 6,006,754) in view of Young or Jandacek (US 4,005,196).

Applicants request reconsideration and withdrawal of the rejection in view of the amendments to the claims and the remarks that follow.

Applicants' method Claim 5 has been amended: to provide that the step of providing a test meal includes a test meal having a predetermined amount of dietary fat and a predetermined amount of sucrose polyester comprising sucrose behenate; to collect a sample portion of fecal matter from the stool of the subject; to analyze for the amount of total fatty acids in the dietary fat and the amount of behenic acid in the sucrose behenate recovered in the fecal sample portion,

and to provide calculating the amount of dietary fat recovered from the test meal based on the measured amounts of total fatty acid and behenic acid.

Janghorbani et al. teach a method for measuring fat digestion and absorption, by feeding a person a labeled (C^{13}) fat, a nonabsorbable marker, and a stool coloring agent, and then homogenizing and measuring in a colored sample of the person's feces, the amount of labeled fat and the amount of nonabsorbable marker. The rejection states that Janghorbani et al. fail to teach that the non-absorbable marker in the test meal can be a sucrose polyester such as sucrose behenate, or that the test meal comprises protein and carbohydrate in addition to the dietary fat and non-absorbable marker. The rejection also states that Jandacek et al. teach non-absorbable, non-digestible liquid polyol polyesters as fat substitutes, where the fatty acids contain 8 to 22 carbon atoms. The rejection notes that one of the numerous fatty acids mentioned is C_{22}. The rejection concludes that it would be obvious to use the polyol polyester compound, sucrose polyester, as the non-absorbable, non-digestible marker of the composition and method of Janghorbani et al. in place of the lanthanide salt marker, since Janghorbani et al. only requires that the marker compound be non-absorbable and non-digestible so that it is excreted in the feces.

Applicants present a Declaration under 37 CFR 1.132 from Dr. Ronald J. Jandacek. In the 132 Declaration, Dr. Jandacek states that Janghorbani et al. describe the measurement of a labeled dietary fat (such as a C^{13}-labeled palmitin) and a lanthanide salt as a non-digestible marker in a colored stool sample from a patient, in order to measure fat digestion and absorption. Dr. Jandacek notes that a labeled fat would have lipophilic properties, while a lanthanide salt is an inorganic compound that is not soluble in lipids. Consequently, the labeled fat and the lanthanide salt marker of Janghorbani et al. have substantially different physical properties of solubility.

Dr. Jandacek also states that Janghorbani et al. describe that the certain lanthanide salt ($DyCl_3$) and labeled triglyceride follow the same excretion kinetics, but that this would only mean that the materials pass through the digestive system at about the same relative rate. In Dr. Jandacek's opinion, the lanthanide salt and any labeled fat would not be miscible or homogenous in the patient's stool, and a person of ordinary skill in the art would expect, from the disparity in physical properties between fat (a lipid) and lanthanide salt (an inorganic salt that is not soluble

in lipid), that these two materials would not disperse homogenously in the stool, thus necessitating the collection and homogenizing of the entire stool before taking a sample for analysis.

Dr. Jandacek goes on to say that Janghorbani et al. describe that "(e)ach stool was transferred to a tared plastic container and weighed accurately" (column 6, lines 6-7), which he understands to say that the entire stool of the patient was collected, and the entire weight obtained. Janghorbani et al. also describes that "the stool is homogenized and a weighed fraction taken for analysis", which Dr. Jandacek understands to say that the entire stool of the patient is first homogenized, and then a portion of the homogenized material is taken for analysis. Dr. Jandacek also notes that the technique described in Janghorbani et al. would be completely consistent with the lanthanide salt and the labeled fat being immiscible or segregating from one another within the fecal material.

Dr. Jandacek continues that the advantage provided in Janghorbani et al. relates to the convenience of coloring the stool so that only a stool that is colored needs to be collected, and to the sampling for analysis of only a small portion of the homogenized colored stool. Janghorbani et al. does not disclose collection of only a small portion of the stool from the patient, from which the sample for analysis is taken, and does not suggest that the method is effective for determining fat absorption without homogenizing the entire stool sample before analysis.

Dr. Jandacek states that he recognized, as a person of skill in this art, that a marker used for studying fat absorption using small fecal samples that are not homogenized, was required to be non-absorbable and non-digestible, but was also required to be co-localizable or miscible with the dietary fat in the stool sample, and that Janghorbani et al. failed to identify this important characteristic which is provided by the sucrose behenate in the method claimed in the present application. On the contrary, dietary fat and sucrose polyester (including sucrose behenate) have the same physical properties (as described in Applicants' paragraph [0030], lines 6-7, and paragraph [0033] lines 7-11), and because they are inherently soluble and miscible in one another, the claimed method enables the collecting of just a small portion of the stool from a subject as a sample, without requiring homogenization.

Consequently, Janghorbani et al. teach a method for measuring fat digestion and absorption, by feeding a person a labeled (C^{13}) fat, a nonabsorbable lanthanide salt marker, and a

stool coloring agent, collecting and then homogenizing the entire colored stool, and taking a sample of the homogenized stool (column 6, lines 6-8), and measuring in the homogenized sample the amount of labeled fat and the amount of nonabsorbable marker.

Turning to Jandacek et al., the disclosure at column 8, lines 7-68 that is relied upon by the Examiner relates to "liquid polyol polyesters". Sucrose behenate is not a liquid polyol polyester. Jandacek et al. does mention at column 7, lines 59-65 that "typical examples of edible, solid, non-absorbable, non-digestible polyester AAL (anti-anal leakage) agents herein include sucrose octastearate, sucrose octapalmitate, sucrose heptastearate, xylitol pentastearate, galactose pentapalmitate, and like, saturated polyol polyesters having at least four -OH groups esterified with C_{10}-C_{22} saturated fatty acids". However, the specifically-exemplified solid sucrose polyesters are not behenate, and there is no inherent disclosure in Jandacek et al. of sucrose behenate. Applicants also note that Jandacek et al. *does not require* a solid sucrose polyester, since C_{12}-C_{24} saturated fatty acids, or materials that yield the same upon hydrolysis in the gut, are other examples of AAL agents.

Consequently, a person of ordinary skill would not understand the disclosure of Jandacek et al. as teaching sucrose behenate; while sucrose behenate is a *possible* solid polyester, it is neither expressly, impliedly or inherently disclosed, nor suggested.

Young discloses a fat composition containing dietary fat and sucrose polyester, and its use in making low moisture foods such as potato chips. Young makes no teaching or suggestion that sucrose polyester comprising sucrose behenate is useful as a marker for measuring fat digestion and absorption.

The rejection, notwithstanding the amendments to the Claim 5, fails to state a *prima facie* obviousness rejection because there does not appear to be any disclosure in either Janghorbani et al. or Young of a "test meal composition", or of identifying an amount of a marker in a fecal sample by measuring fatty acids, and specifically the total fatty acids and the behenic acid.

There is also a lack of any motivation disclosed within either Janghorbani et al. or Young (or Jandacek et al.) to combine the references. Janghorbani et al. describes the marker as a "non-absorbable and non-digestible" material. Applicants note that there are scores of ingestible

materials that would quality as "non-absorbable and non-digestible", including silica, dietary fiber, and TiO_2, all known to be found in food compositions and ingredients. None of these other ingestible, non-absorbable materials was known as a marker for measuring fat digestion and absorption. Sucrose behenate, although known to be "non-absorbable and non-digestible", was not known to be a fat absorption marker. This suggestion for using sucrose polyester comprising sucrose behenate as a marker (for measuring fat digestion and absorption) has not been taught or suggested by the cited prior art references, but is provided only in Applicants' own description.

The method of Janghorbani et al. also expressly requires that the entire colored stool of the patient is collected, and the entire stool is first homogenized before a sample for analysis is obtained. A person of ordinary skill in the art would expect that the disparity in physical properties between fat (a lipid) and the lanthanide salt (an inorganic salt that is not soluble in lipid) would not disperse homogenously in the stool, thus establishing the need for collection and homogenizing of the entire stool, before taking a sample for analysis.

On the contrary, dietary fat and sucrose polyester (including sucrose behenate) have the same physical properties (Applicants' paragraph [0030], lines 6-7, and paragraph [0033], lines 7-11), and are inherently soluble and miscible in one another. This feature of the invention enables the collecting of just a small portion of the stool from a subject as a sample for analysis, rather than the entire stool, and without any need to homogenize the stool or the collected sample. Applicants' disclosure at paragraphs [0058] – [0061] (Examples 4 and 5) describes that the results obtained by the claimed method (using sucrose behenate) do not differ by a statistically significant degree from a method that uses fecal homogenates and from the fat balance method, yet they provide a significant advantage over the prior art in terms of sample collection, patient convenience, and patient compliance.

Furthermore, the method of Janghorbani et al. requires a labeled triglyceride, and that "the chain-length, degree of saturation and position of labels on the fatty acids of selected triglycerides determine the sensitivity and specificity of the invention method and formulation to various disorders of fat maldigestion and fat malabsorption." (column 4, line 66 – column 5, line 3). The labeled triglyceride of Janghorbani et al. is an essential component of the disclosed composition and method, and a composition that does not contain a labeled fat would change the principle of operation of the Janghorbani et al. reference. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention

being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)

CONCLUSION

Applicants believe that a complete response to the rejections has been made, and that the claims as amended distinguish the prior art of record, and places the application into condition for allowance, or at least into better condition for an appeal of the rejection.

Respectfully submitted,

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